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| 09/852,408 | 05/09/2001 | Carlos Schuler | 0064.00 | 5388 |

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

| EXAMINER | |
|---|---|
| PATEL, NIHIR B | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/852,408 | SCHULER ET AL. | |
| | Examiner | Art Unit | |
| | NIHIR PATEL | 3772 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03.13.2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed on March 13th, 2008 have been fully considered but they are not persuasive. The applicant argues that Burns does not disclose an electronic prevention device which prevents manual activation of a drug formulation when in an inactive state and which permits manual actuation when an electric current is supplied to place the prevention device in an activated state. The examiner disagrees with the applicant's argument. Burns does disclose an electronic prevention device **24 (the controller being the electronic prevention device)** which prevents manual activation of a drug formulation when in an inactive state **(Burns states that "The controller would signal the actuator means 28 to lock up and prevent actuation of the inhalation device after the requisite number of actuations have occurred and during the periods when actuation is not suppose to occur" (see col. 8 lines 20-30); the device comprises manual activation because you are pressing down on the canister 10)** and which permits manual actuation when an electric current is supplied to place the prevention device in an activated state **(Burns states that the actuator means 28 to lock up and prevent actuation of the inhalation device after the requisite number of actuations" implying that the controller 24 permits manual activation when an electric current is supplied to place the prevention device in an activated state)**.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-13, 15, 16 and 28-33** are rejected under 35 U.S.C. 102(b) as being anticipated by Burns et al. (US 5,284,133).

4. **As to claim 1,** Burns teaches an apparatus that comprises a disposable container **10 (see figure 1; column 7 lines 50-55)** adapted to contain a drug formulation; an aerosol generator for aerosolizing the drug formulation in response to manual actuation **(see column 7 lines 50-65)**; and an electronic prevention device **24 (see figure 1 and column 8 lines 10-20)** which prevents manual activation thereby preventing aerosolization of the drug formulation when in an inactive state and which permits manual actuation thereby permitting aerosolization of the drug formulation when an electric current is supplied to place the prevention device in an activated state **(see column 8 lines 20-30)**.

5. **As to claim 2,** Burns teaches an apparatus wherein the prevention device comprises an electronic lockout device having a lockout element that is positioned in a dose preventing position when in an inactive state, and is movable to a dosing permitting position when electronic current is supplied to place the lockout device in the activated state **(see columns 8 and 9)**.

6. **As to claim 3,** Burns teaches an apparatus wherein the lockout device further comprises circuitry for supplying electrical current to move the lockout element to the dose permitting position when the lockout device is in the activated state **(see column 8 lines 55-67)**.

7. **As to claim 4,** Burns teaches an apparatus wherein the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the

controller is configured to send a signal to place the lockout device in the activated state only after the dosing condition has been satisfied **(see column 8 lines 1-30)**.

8. **As to claim 5,** Burns teaches an apparatus wherein the container comprises a canister **10 (see figure 1; column 7 lines 50-55)**, and wherein the aerosol generator comprises a metering valve **12** and an actuator **28** operably coupled to the canister **(see column 7 lines 50-60 and column 9 lines 9-20)**.

9. **As to claim 6,** Burns teaches an apparatus that further comprises a housing, wherein the canister is reciprocally held within at least a portion of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve and to permit the escape of metered amount of the drug formulation from the canister **(see column 7 lines 50-60 and column 8 line 10-20)**.

10. **As to claim 7,** Burns teaches an apparatus wherein the lockout device is positioned to prevent engagement of the actuator when in the dose preventing position to thereby prevent opening of the metering valve **(see column 10 lines 25-45)**.

11. **As to claim 8,** Burns teaches an apparatus wherein the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing when the lockout element is in the dose prevention position **(see column 10 lines 50-60)**.

12. **As to claim 9,** Burns teaches an apparatus wherein upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing and to permit engagement of the actuator to open the metering valve **(see column 10 lines 50-60)**.

13. **As to claim 10,** Burns teaches an apparatus wherein the canister is movable within the housing when the preventing device in the inactive state, and further comprising a stop that is reciprocally disposed within the housing below the actuator, and wherein the lockout element has a distal end that is engageable with the stop when in the activated state to prevent movement of the stop within the housing such that displacement of the canister engages the actuator with the stop to permit dispensing of the metered drug formulation when the preventing device is in the activated state **(see column 9 lines 40-60)**.

14. **As to claim 11,** Burns teaches an apparatus that further comprises a high pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state **(see column 7 lines 50-60)**.

15. **As to claim 12,** Burns teaches an apparatus that further comprising a dose counter disposed to count the number of doses of the drug formulation dispensed from the container **(see column 9 lines 40-60)**.

16. **As to claim 13,** Burns teaches an apparatus wherein the container is reciprocatably disposed within the housing, and wherein the dose counter comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing **(see column 9 lines 40-60)**.

17. **As to claim 15,** Burns teaches an apparatus that further comprises a nozzle operably coupled to the canister, and wherein the housing further includes a mouthpiece **14** disposed to receive the drug formulation from the nozzle **(see column 7 lines 50-60)**.

18. **As to claim 16,** Burns teaches an apparatus wherein the mouthpiece has a first end and a second end, and wherein the nozzle is positionable within an opening adjacent the first end of the

mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece **(see figure 1)**.

19. **As to claim 28,** Burns teaches an apparatus that comprises a housing having a mouth piece **14 (see figure 1)**; a canister **10 (see column 7 lines 40-60)** that is movable within the housing when manually depressed **(see column 7 lines 40-60)** into the housing, the canister having a metered valve that is operable to release a metered amount of a drug formulation from the canister **(see column 7 lines 40-60)**; and a control system **24 (see column 8 lines 10-20)** comprising a locking mechanism that may be in an activate or an inactivate state, wherein the control system controls the opening of the valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time the locking mechanism in the active state **(see columns 8 and 9)**.

20. **As to claim 29,** Burns teaches an apparatus wherein the control system comprises a controller, wherein the controller is configured to send a signal to the locking mechanism to activate the locking mechanism to permit opening of the valve once the dosing condition has been satisfied **(see column 8 lines 10-20)**.

21. **As to claim 30,** Burns teaches an apparatus wherein the dosing condition is the passage of certain amount of time between dosings, and further comprising an electronic clock coupled to the controller to measure the passage of time between dosings **(see columns 8 and 9)**.

22. **As to claim 31,** Burns teaches an apparatus wherein the locking mechanism is normally in a dose preventing position and is movable to a dosing position when electrical current is supplied to the locking mechanism to permit opening of the valve when the canister is depressed **(see column 8)**.

23. **As to claim 32,** Burns teaches an apparatus wherein the locking mechanism includes a locking element that engages the canister to prevent depression of the canister into the housing when in the dose preventing position **(see column 8)**.

24. **As to claim 33,** Burns teaches an apparatus wherein the canister includes an actuator **28** and wherein the locking mechanism includes a locking element that engages a stop that in turn engages the actuator when in the dose permitting position and when the canister is depressed into the housing **(see column 7 lines 40-60)**.

***Claim Rejections - 35 USC § 103***

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. Claims **17-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133).

28. **As to claims 17-27,** Burns substantially discloses a method step of providing a container having an amount of a drug formulation that is aerosolized in response to manual operation **(see column 7 lines 40-60)**; preventing the manual actuation of the aersolization of the drug formulation with an electronic lockout device by maintaining the lockout device is in an inactive state **(see column 8)**; and supplying electrical current to the lockout device to place the lockout device in an active state, thereby permitting the manual actuation of the aersolization of the drug formulation **(see columns 8 and 9)**.

The method steps would have been obvious because they would have resulted from the use of the device of Burns.

29. Claims **14 and 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133) in view of Nilsson et al. (US 4,934,358).

30. **As to claim 14,** Burns substantially discloses the claimed invention; see rejection of claims 1 and 13 above, but does not disclose a dose counter that comprises a display for indicating if the container contains an amount of drug formulation. Nilsson teaches an apparatus that does provide a dose counter that comprises a display for indicating if the container contains an amount of drug formulation **(see column 4 lines 30-50)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Burns's invention by providing a dose counter that comprises a display for indicating if the container contains an amount of drug formulation as taught by Nilsson in order to supply information about the number of doses given.

31. **As to claims 34-35,** Burns substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a container that contains a drug formulation which

comprises nicotine. Nilsson teaches an apparatus that does disclose a container that contains a drug formulation that comprises nicotine **(see column 1 lines 40-50)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Burns's invention by providing a container that contains a drug formulation which comprises nicotine as taught by Nilsson in order to prevent gastrointestinal secondary effects and facilitating nicotine therapy in antidotal smoking treatment of persons with chewing difficulties.

The method steps would have been obvious because they would have resulted from the use of the device of Burns.

32. Claim **36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133) in view of Nilsson et al. (US 4,934,358).

33. **As to claim 36,** Burns substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a container that contains a drug formulation which comprises nicotine. Nilsson teaches an apparatus that does disclose a container that contains a drug formulation that comprises nicotine **(see column 1 lines 40-50)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Burns's invention by providing a container that contains a drug formulation which comprises nicotine as taught by Nilsson in order to prevent gastrointestinal secondary effects and facilitating nicotine therapy in antidotal smoking treatment of persons with chewing difficulties.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772